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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/834,442 04/13/01 WHITAKER

J 29342/37225

EXAMINER

004743 HM12/0815
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ART UNIT

PAPER NUMBER

1617

5

DATE MAILED:

08/15/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/834,442

Applicant(s)

WHITAKER ET AL.

Examiner

Mojdeh Bahar

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 14-18 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☒ Claim(s) 5-13 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

This application is a CIP of 09/558911 filed on April 26, 2000.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-13, drawn to an article of manufacture comprising an oral dosage form comprising PDE-5 inhibitor, a package insert and a container, classified in class 514, subclass 287, for example.
- II. Claims 14-16, drawn to a method of treating erectile dysfunction, classified in class 514, subclass, 287, for example.
- III. Claims 17-18, drawn to a method of improving a relaxant response in corpus cavernosum smooth muscle, classified in class 514, subclass 287, for example.

Inventions I and II-III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case erectile dysfunction can be treated and a relaxant response in corpus cavernosum smooth muscle can be improved by using phentolamine, prostoglandins.

Specie Election

Claims 1-18 are generic to a plurality of disclosed patentably distinct species of PDE-5 inhibitors. Claims 1-18 as presented contain such a vast multitude of possibilities of PDE-5 inhibitors that the search for each and every species encompassed in the claims presents an undue burden on the office. Accordingly, a requirement to provisionally elect a single

independent and patentably distinct species is made as provided for in MPEP 803.02. These species are considered to be distinct inventions since the species are so diverse and unrelated structurally that a reference anticipating one of the species would not anticipate or render obvious the other species. Thus, the stated species are capable of supporting separate patents. These compounds are classified in different subclasses the search of which imposes an undue burden on the office. Note that the search is not limited to the patent files.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, **one specific compound**, even though this requirement is traversed.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with James Napoli on August 7, 2001 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-13, and the compound of claim 13 as the elected specie. Affirmation of this election must be made by applicant in replying to this Office action. Claims 12 and 14-18 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected specie and invention.

Claims 1-11 and 13 are examined on the merits herein in so far as they read on the elected species.

Claim Objections

Claims 5-13 are objected to under 37 CFR 1.75(c) as being in improper form because multiple dependent must refer to the claims in the alternative. See MPEP § 608.01(n). Claims 5-13 are dependent from claims "1 through 4". Accordingly, claims 5-13 have not been further treated on the merits.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 3,6-8, 13-17 of copending Application No. 09/558911. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference in the two applications is the package insert and the dosage.

The optimization of amounts are within the skill of the artisan and are therefore obvious. Moreover, the inclusion of a package insert including "indications and use" of the pharmaceutical composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art. (See *Remington's: the Science and Practice of Pharmacy*, Nineteenth Edition, Vol. 1, page 806). Further, the particular package insert precautions herein are motivated by the prior art since selective PDE5 inhibitors would have been reasonably expected to exhibit the therapeutic activity for treating erectile dysfunction known for PDE5 inhibitors, while at the same time producing additional or reduced side effects related to interaction with other additional receptors.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daugan et al. (WO 96/32003) in view of the abstract of Neiwohner et al. (WO 99/24433).

Daugan et al. (WO 96/32003) teaches a pharmaceutical composition comprising a PDE-5 inhibitor compound of formula I, see abstract. Daugan et al. (WO 96/32003) teaches that its pharmaceutical composition can be used to treat erectile dysfunction, see particularly page 7, line 34 and page 8 line 1. Daugan et al. (WO 96/32003) shows that the compounds of formula I exhibit an IC₅₀ value of less than 10 nM, see particularly Table 1. Daugan et al. (WO 96/32003) also teaches that the preferred route of administration is oral, and that the dosage range is from 0.5-800 mg, individual tablets contain from 0.2-400 mg of the active compound in a suitable pharmaceutically acceptable carrier, for administration in single or multiple doses, once or several times per day, see particularly page 9, lines 5-11. Daugan et al. (WO 96/32003) also teaches that its pharmaceutical composition can be used in treating cardiovascular disorders, e.g. conditions of reduced blood vessel patency, peripheral vascular disease, see particularly page 7, lines 21 to page 8, line 2.

Daugan et al. (WO 96/32003) does not teach the inclusion of a package insert or a container.

Neiwohner teaches 2-phenyl substituted imidazotriazinones (including sildenafil and vardenafil) are suitable for use as active agents in medicaments for treating cardiovascular and cerebrovascular diseases, see abstract and example 19.

It would have been obvious to one of ordinary skill at the time the invention was made to include the PDE-5 active herein in a container and to include the package insert herein for the therapeutic composition.

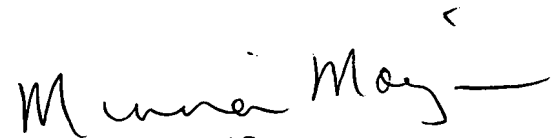
One of ordinary skill in the art would have been motivated to include the therapeutic agent comprising PDE5 in a container since the packaging of pharmaceutical compositions is widely practiced in the art and is therefore within the skill of the artisan. Moreover, the inclusion of a package insert including "indications and use" of the pharmaceutical composition is mandated by 21 CFR 201.57 and is therefore obvious to one of ordinary skill in the art. (See *Remington's: the Science and Practice of Pharmacy*, Nineteenth Edition, Vol. 1, page 806). Further, the particular package insert precautions herein are motivated by the prior art since selective PDE5 inhibitors would have been reasonably expected to exhibit the therapeutic activity for treating erectile dysfunction known for PDE5 inhibitors, while at the same time producing additional or reduced side effects related to interaction with other additional receptors.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from 8:30 a.m. to 6:30 p.m. Monday, Tuesday, Thursday and Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar
Patent Examiner
August 10, 2001


MINNA MOEZIE, J.D.
SUPERVISORY PATENT EXAMINER
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